Mobile Medical Apps and the FDA

Mobile Medical Apps

- September 2013 "Final" Guidance: How the FDA intends to regulate software applications intended for use on mobile platforms.
- Broad categories
  1. Unregulated apps considered outside of FDA's jurisdiction
  2. Apps considered within FDA jurisdiction but where FDA will exercise enforcement discretion and refrain from regulation on the basis of low patient risk
  3. Regulated apps

- February 2015 "Final Final" Guidance--Superseded September 25, 2013 Guidance
  - Updated to be consistent with a February 2015 guidance document on the low risk of MDDS (down-classified).
  - "Although the FDA has not issued an overarching software policy, the Agency has formally classified certain types of software applications that meet the definition of a device and, through classification, identified specific regulatory requirements that apply to these devices and their manufacturers."
    - FDA regulates "by function, not by platform"

Definitions

- Mobile Platform
  - Commercial off-the-shelf computing platforms, with or without wireless connectivity, that are handheld in nature. Examples of these mobile platforms include mobile computers such as smart phones, tablet computers, or other portable computers.
- Mobile Application (Mobile App)
  - A software application that can be executed on a mobile platform (i.e., a handheld commercial off-the-shelf computing platform, with or without wireless connectivity), or a web-based software application that is tailored to a mobile platform but is executed on a server.

Definitions

- Mobile Medical Application (Mobile Medical App)
  - For purposes of this guidance, a "mobile medical app" is a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) 4; and either is intended:
    - to be used as an accessory to a regulated medical device; or
    - to transform a mobile platform into a regulated medical device.

Mobile apps that FDA does not consider to be devices

- Mobile apps that are intended to provide access to electronic "copies" (e.g., e-books, audio books) of medical textbooks or other reference materials with generic text search capabilities.
- Mobile apps that are intended for health care providers to use as educational tools for medical training or to reinforce training previously received.

- Mobile apps that are intended for general patient education and facilitate patient access to commonly used reference information. These apps can be patient-specific (i.e., filters information to patient-specific characteristics), but are intended for increased patient awareness, education, and empowerment, and ultimately support patient-centered health care.
- Mobile apps that automate general office operations in a health care setting and are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.
- Mobile apps that are generic aids or general purpose products.

Enforcement Discretion Mobile Medical Apps

- Help patients self-manage their disease or conditions without providing specific treatment or treatment suggestions;
- Provide patients with simple tools to organize and track their health information;
- Provide easy access to information related to patients' health conditions or treatments;
- Help patients document, show, or communicate potential medical conditions to health care providers;
- Automate simple tasks for health care providers;
- Enable patients or providers to interact with Personal Health Record (PHR) or Electronic Health Record (EHR) systems; or
- Intended to transfer, store, convert format, and display medical device data in its original format from a medical device.

Mobile Medical Apps

- Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices.
  - Mobile apps that use attachments, display screens, sensors or other such similar components to transform a mobile platform into a regulated medical device are required to comply with the device classification associated with the transformed platform.

- Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations. These types of mobile medical apps are similar to or perform the same function as those types of software devices that have been previously cleared or approved.
  - Apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy; Computer Aided Detection software image processing software; and radiation therapy treatment planning software.

Most recently cleared "MMAs" at FDA site

Device Name	Clearance Date	Regulation Description
Stethee Pro	10/30/2017	Stethoscope ("The World's First Artificially Intelligent Enabled Stethoscope System")
Biim Diagnostic Ultrasound System	10/27/2017	Ultrasonic pulsed echo imaging system.
DentureID Microchip	10/25/2017	Implantable radiofrequency transponder system for patient identification and health information.
Avail	10/19/2017	Transcutaneous electrical nerve stimulator for pain relief.
ECG SENTINEL System	10/18/2017	Telephone electrocardiograph transmitter and receiver.
SONON Ultrasound Imaging System, Model: 300L	10/12/2017	Ultrasonic pulsed doppler imaging system.
Higi Station (With Body Composition and Pan and Tilt Cuff Housing), Higi Station (With Body Composition and Fixed Cuff Housing)	10/10/2017	Noninvasive blood pressure measurement system.
MSA100BT Peak Flow Meter	10/6/2017	Peak-flow meter for spirometry.
ECG Check - Universal, ECG Check - Universal Plus	10/2/2017	Telephone electrocardiograph transmitter and receiver.

21st Century Cures Act (December 2016)

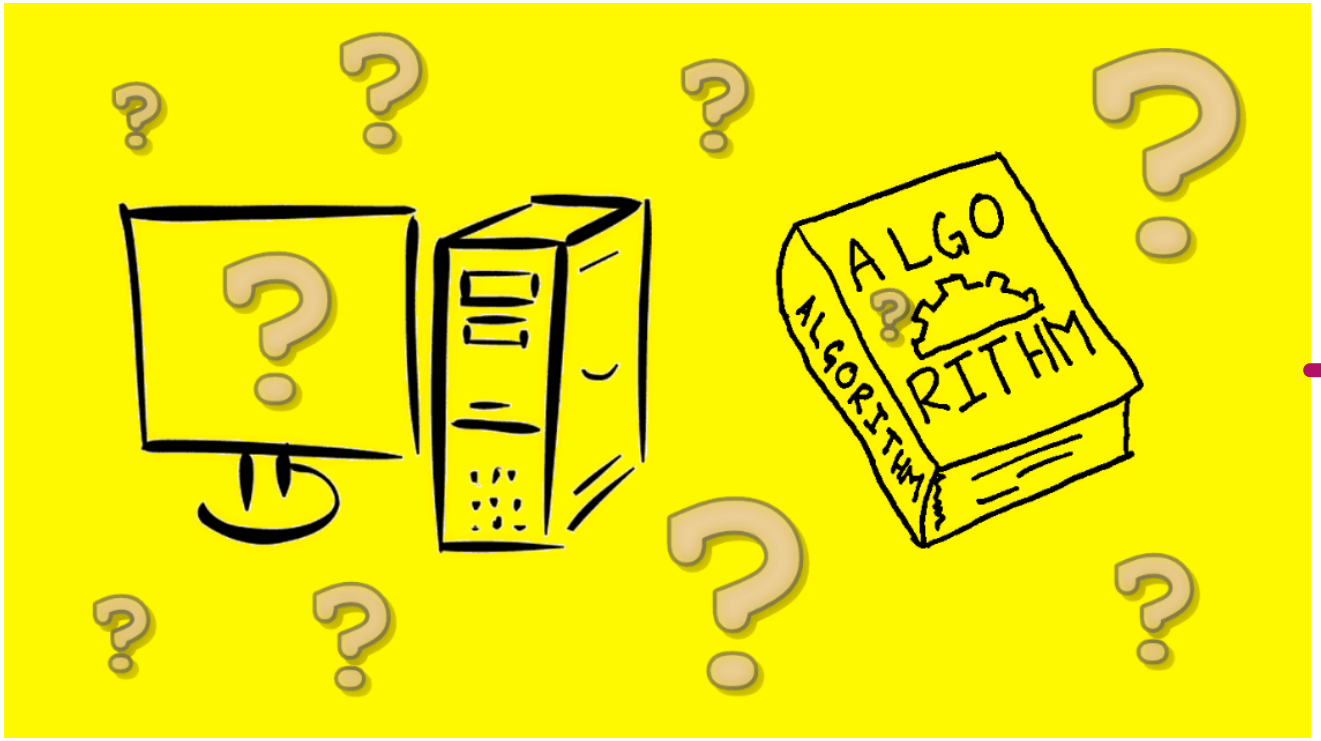
- Section 3060. Modifies the definition of "device" to remove a number of categories of software from FDA's jurisdiction.
  - Software that provides administrative support of a healthcare facility.
  - Software for maintaining or encouraging a healthy lifestyle, and not related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.
  - Software that serves as electronic patient records, provided that such function is not intended to interpret or analyze patient data or images for the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.
  - Software for transferring, storing, converting formats, or displaying data/results and associated findings by a healthcare professional (e.g., MDDS), unless intended to interpret or analyze the data, results or findings.

- Software for:
  - (i) displaying, analyzing, or printing medical information about a patient or other medical information;
  - (ii) supporting or providing recommendations to a healthcare professional (i.e., clinical decision support) about prevention, diagnosis or treatment of a disease or condition, AND
  - (iii) enabling the health professional to independently review the basis for such recommendations rather than primarily rely on it when making diagnostic and treatment decisions.

Claw-back potential

- FDA can regain jurisdiction if it believes that the software at issue "would be reasonably likely to have serious adverse health consequences."
- FDA must issue a final order in the Federal Register providing its rationale based upon the potential for and severity of patient harm if the software does not perform as intended, **the extent to which the software is intended to support the judgment of a healthcare professional, whether a healthcare professional has a reasonable opportunity to review the basis of the information or treatment recommendation provided,** and the intended user and use environment.

What's in the black box?



→ **“Do this, not that”**

Post-Cures Act FDA Reactions

- "Final final" Mobile Medical Apps Guidance now has the following "face sheet":
  - The 21st Century Cures Act (12/13/2016) amended the definition of "device" in the Food, Drug and Cosmetic Act to exclude certain software functions, including some described in this guidance document. FDA is assessing how to revise this guidance to represent our current thinking on this topic. For additional information, contact digitalhealth@fda.hhs.gov or refer to https://www.fda.gov/MedicalDevices/DigitalHealth/default.htm

- New Guidance Documents Issued December 8, 2017
  - Software as a Medical Device (SAMD): Clinical Evaluation - Guidance for Industry and Food and Drug Administration Staff
  - Clinical and Patient Decision Support Software - Draft Guidance for Industry and Food and Drug Administration Staff
  - Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act - Draft Guidance for Industry and Food and Drug Administration Staff

SAMD Guidance

- Consists of and adopts internationally converged principles agreed upon by IMDRF.
  - "Initial framework when further developing FDA's specific regulatory approaches and expectations for regulatory oversight."
  - Does not provide recommendations for FDA Staff and Industry to apply to specific regulatory situations, nor does it modify current regulatory expectations, including those for regulatory submissions, at this time.
- IMDF paper describes a converged approach for planning the process for clinical evaluation of SAMD as "software with a medical purpose," which performs the purpose without being part of a hardware medical device.
  - "Medical purpose"—analogous to FDA medical device "purposes" but broader.

CDSS Guidance

- Sets forth Cures Act changes
- CDS = software functions that meet the first, second, and third criteria of the Cures Act.
- Not always excluded from the device definition by the Cures Act.
  - Excluded only when a function also meets the fourth criterion (enabling independent review of the basis for recommendations).
    - User should be able to reach the same recommendation on their own without relying primarily on the software function.
    - Sources supporting the recommendation or underlying the rationale for the recommendation should be identified and easily accessible to the user, understandable by the user, and publicly available.

Cures Act Changes Guidance

- Explains Cures Act categories of excluded former devices
  - Primarily "Stuff FDA Already Didn't Care About"
    - Exception—CDSS with black boxes
- Will modify MMA guidance and other guidance documents as applicable